

REMARKS

Claim 1 was examined and is the only claim pending in the present application. Claim 1 was rejected as being anticipated by and/or obvious over U.S. Patent Nos. 4,554,156; 5,853,749; and PCT Publication No. WO 96/04025. This rejection was final. Reexamination and reconsideration of claim 1, as amended, are respectfully requested.

Rejection under USC §102(a):

Claim 1 was rejected under USC §102(a), as allegedly being anticipated by Hobbs, WO 96/04025 (hereinafter the '025 application). The Examiner characterizes the '025 application as disclosing gel wound dressings comprising gel particles to absorb wound exudate that are applied with a syringe. Applicants' claim 1 includes a hydrogel present in an applicator having an extrusion orifice wherein the hydrogel has been fragmented by mechanical disruption. To differentiate Applicants' claim 1 from the cited reference, claim 1 has been amended to add the limitation that the extrudable fragmented biocompatible hydrogel also be resorbable. By "resorbable" it is meant that the composition will degrade or solubilize, when placed directly into a target site in a patient's body.

In contrast, the '025 application does not describe the hydrogel as resorbable. Although the '025 application does mention the use of a syringe to introduce a gel into a deep wound on page 4, this application does not describe or suggest a hydrogel in the syringe that is resorbable. For example, on page 3 of the '025 application it states, "*In addition to facilitating manipulation, a relatively low viscosity can enable the tackiness of the material to be maintained relatively low, which reduces damage to the wound when the dressing is removed.*" Further on page 10 of the '025 application, it states, "*It is envisaged that, in most circumstances, the dressing will be changed after a period of, perhaps, hours or days...*" One skilled in the art would assume that the dressing of the '025 application must be removed because it is not resorbable.

The '025 application describes a gel that is removed from tissue and is not resorbable. Because the '025 application does not describe or suggest a hydrogel as claimed in claim 1, the hydrogel of claim 1 is patentable over the cited reference.

Rejection under USC §102(b)

Claim 1 was rejected under USC §102(b), as allegedly being anticipated by *Fischer et al.*, U.S. Patent No. 4,554,156 (hereinafter the '156 patent). The Examiner characterizes the '156 patent as disclosing a wound-treating agent comprising gel particles that swell with water to form a barrier which is impermeable to bacteria and bars the entry of pathogens to the wound that are applied with a syringe. As set forth above, Applicants' claim 1 has been amended to add the limitation that the extrudable fragmented biocompatible hydrogel also be resorbable.

In contrast, the '156 patent describes a material that is removed from tissue. For example, the powder is described as having, "*swollen particles stick together in such a manner that they not only form a coherent mass which can easily be removed again from the wound, but also form a barrier...*" (Col. 2, lines 18-21) The powder is further described as having the property that, "*when in a swollen state, develops so great an adhesive force that, in most cases, it can be completely removed from the wound by rinsing out.*" (Col. 2, lines 65-67) As stated above, resorbable materials do not require removal from tissue, and the gel claimed by claim 1 of the present invention differs from the cited reference in this respect.

The '156 patent describes a gel that is removed from tissue and is not resorbable. Because the '156 patent does not describe or suggest a hydrogel as claimed in claim 1, the hydrogel of claim 1 is patentable over the cited reference.

Rejection under USC §102(e):

Claim 1 was rejected under USC §102(e), as allegedly being anticipated by *Hobbs*, U.S. Patent No. 5,853,749 (hereinafter the '749 patent). The Examiner relies on the '749 patent as disclosing gel-wound dressings comprising gel particles to absorb wound exudate that are applied with a syringe. The Applicants' claim 1 includes a hydrogel in an applicator that is resorbable as set forth above. In contrast, the '749 patent does not describe the hydrogel as being resorbable. Although the '749 patent describes "*a highly mobile gel being suitable for introduction into a deep wound by a syringe,*" (Col. 3, lines 40-41), this patent does not describe or suggest the gel in the syringe (applicator) is resorbable as set forth in claim 1. For example, the '749 patent states, "*It is envisaged that, in most circumstances, the dressing will be changed after a period of, perhaps, hours or days, according to the condition of the wound, for example, about 2 to 3 days...*" (Col. 6, lines 61-64) The '749 patent also states, "*When the dressing is to be changed, the gel-like characteristics*

of the dressing material facilitate its removal from the wound, . . .” (Col. 6, line 67 to Col. 7, line 2)
These statements indicate that the gel of the ‘749 patent is changed, and is therefore not resorbable.

The ‘749 patent describes a gel that is removed from tissue and is not resorbable. Because the ‘749 patent does not describe or suggest a hydrogel as claimed in claim 1, the hydrogel of claim 1 is patentable over the cited reference.

Rejection under USC §103

The Examiner relies on the ‘025 application, the ‘749 patent, and the ‘156 patent to form the basis of a rejection under USC §103. In order to establish a *prima facie* case of obviousness, the prior art must teach all claim limitations. None of the patents relied upon by the Examiner describe or suggest a gel that is resorbable. Therefore, the resorbable hydrogel of claim 1 is patentable over the references relied upon by the Examiner.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Attached is a marked-up version of the changes made to claim 1 by the current amendment. The attached page is captioned with “VERSION WITH MARKINGS TO SHOW CHANGES MADE.”

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at 650/326-2400.

Respectfully submitted,


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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend claim 1 as follows:

- 1 1. (Twice Amended) An extrudable fragmented biocompatible resorbable
2 hydrogel which is substantially free from an aqueous phase, said hydrogel being present in an
3 applicator having an extrusion orifice, wherein the hydrogel has been fragmented by mechanical
4 disruption.